Supreme Court, U.S.
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No. 95-

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

RULE 29.6 STATEMENT

Petitioner Medtronic, Inc. has no parent corporation and has no nonwholly owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

Petitioner Medtronic, Inc. hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case. The Eleventh Circuit held that state common law claims alleging defects in the design of a medical device were not preempted, even though those claims would establish state law design requirements different from, and in addition to, design requirements imposed under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-395 (1994).

OPINIONS BELOW

The opinion of the court of appeals (App. 1a) is reported at 56 F.3d 1335 (11th Cir. 1995). The opinion of the United States District Court for the Middle District of Florida

granting summary judgment against respondents (App. 1b) is not reported.

JURISDICTION

The court of appeals entered judgment on July 3, 1995. Medtronic filed a timely petition for rehearing and suggestion of rehearing in banc on July 24, 1995, which the court of appeals denied on August 15, 1995. This Court has jurisdiction under 28 U.S.C. § 1254(1) (1988).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix (App. 1f) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 360(k), 360k (1994); 21 C.F.R. §§ 807.81(a)(3), 807.87, 808.1(d) (excerpt), 870.3680(b), (c) (1995).

STATEMENT OF THE CASE

In direct conflict with two other circuits, the Eleventh Circuit held that the FDCA does not preempt state common law claims arising from a medical device's design, even though the federal Food and Drug Administration had reviewed and affirmatively authorized that design for marketing pursuant to the FDCA. This petition asks this Court to review a question of profound significance to all manufacturers and users of rapidly advancing medical device technology—whether manufacturers may be held liable under state law for alleged defects in a medical device design authorized by federal law.

A. Background and Significance of the Federal Law Question

In 1976, Congress passed the Medical Device Amendments to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Under the Medical Device Amendments, the United States Food and Drug Administration ("FDA") has extensive authority to ensure the safety and effectiveness of medical devices. Congress enacted the Medical Device Amendments as "a balanced regulatory proposal" intended to assure both that the public's health is protected and that "innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Through the Medical Device Amendments, Congress sought to encourage research and development of "sophisticated, critically important medical devices," as well as to give the FDA the necessary authority to ensure the public's health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. The technological innovations spawned under this regulatory scheme have been substantial; in 1990, Congress estimated that 5,000 new medical devices enter the market each year under the FDA's authority. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307.

Consistent with the congressional intent to promote innovation by eliminating unnecessary regulation, the Medical Device Amendments include the following express preemption provision:

> Except as provided in subsection (b) . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994).[1] The House committee report for the Medical Device Amendments describes the preemption provision as a "general prohibition on non-Federal regulation," making clear that Congress intended broad preemption of state law under section 360k. H.R. Rep. No. 853, at 45.

The federal requirements giving rise to preemption under section 360k are extensive. Under the FDCA, the FDA regulates medical devices in the context of a classification scheme that distinguishes among devices based upon the concerns they raise about safety and effectiveness. The FDA assigns medical devices intended for human use to one of three classes, effectuating its classification decision through notice and comment rulemaking procedures. *See* 21 U.S.C. § 360c(b)(1) (1994); 21 C.F.R. § 860.84 (1995). Class I devices, which the FDA believes pose no unreasonable health risks, are subject to general controls designed to ensure that labeling is accurate and the product is safe when used as directed. *See* 21 U.S.C. § 360c(a)(1)(A) (1994). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). These special controls may include performance standards, postmarket surveillance, patient registries, and other requirements the FDA deems appropriate. *Id.* The present case involves a Class III device. In general, Class III devices are

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[1] The exception in subsection (b) permits states to apply for an exemption from the preemption imposed by subsection (a). *Id.* § 360k(b).

those represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

The regulatory structure established by the Medical Device Amendments requires the FDA to review and authorize distribution of new medical devices. The FDA conducts this review under one of three clearance processes. First, the FDA regulates clinical experimentation with new devices through the investigational device exemption ("IDE") process. In order to obtain FDA approval for a clinical experiment, the sponsor must submit an IDE application containing significant information about the device and a proposed experimental plan. The FDA then reviews and, if appropriate, approves the application, which authorizes distribution of the device solely for experimental use. *See id.* § 360j(g).

Second, through the premarket approval process, the FDA authorizes marketing of some Class III devices to the general public. To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. *See id.* § 360e(c), (d). As the court of appeals below explained, the premarket approval process involves the most stringent regulatory review undertaken by the FDA. *See* App. 4a.

A third clearance process applies to other Class III devices, such as the one at issue in this case, for which no PMA is required until specifically called for by regulation. *See* 21 U.S.C. § 360e(a)(1) (1994). Until the FDA decides that PMAs are necessary, these Class III devices are subject to FDA premarket clearance through the "510(k)" process be-

fore they may be marketed legally under the FDCA. This process is established by, and named after, section 510(k) of the FDCA, 21 U.S.C. § 360(k). Through the 510(k) process, FDA determines whether devices are substantially equivalent to "preamendment" devices marketed prior to the adoption of the Medical Device Amendments in 1976. The 510(k) substantial equivalence determination is designed to ensure that new devices are as safe and effective as preamendment devices. *See* H.R. Rep. No. 853, at 36-37 (explaining that substantial equivalence determination involves safety and effectiveness determination). Because Class II and some Class I devices also enter the market through the 510(k) process, *cf.* 21 C.F.R. § 860.95(a) (1995), the FDA subjects a substantial number of devices to 510(k) review. Congress noted in 1990 that "98 percent of the estimated 5,000 devices that enter the market every year" do so through the 510(k) process. H.R. Rep. No. 808, at 14, *reprinted in* 1990 U.S.C.C.A.N. 6307.

Under the 510(k) process, Class III device manufacturers such as Medtronic must submit significant information—including design information—proving substantial equivalence before the FDA will authorize marketing. *See* 21 C.F.R. § 807.87. The 510(k) process also imposes significant requirements restricting changes in device design. If a device is cleared for marketing through the 510(k) process, the manufacturer may not change the device design in a manner that could affect safety or effectiveness significantly without an additional 510(k) clearance by the FDA. *See id.* § 807.81(a)(3)(i).

The medical device at issue in the present case is a Model 4011 cardiac pacemaker lead, which is part of a pacemaker system implanted in the body to assist the heart's natural beat. Pacemaker leads such as the Model 4011 transmit small electrical pulses to the heart from another part of the implanted system—a pacemaker pulse generator—and return

signals from the heart to the pulse generator. Pacemaker leads of the type at issue in this case are Class III devices for which no PMA is yet required. *See id.* § 870.3680(b), (c).

Petitioner Medtronic submitted a 510(k) application for the Model 4011 lead to the FDA, and the FDA required additional design information before it would make a decision on the application. On November 30, 1982, the FDA issued its substantial equivalence determination, which authorized marketing of the Model 4011 lead manufactured with the design reviewed and cleared by the FDA. *See* App. 6a.

B. This Litigation

On March 8, 1993, respondents filed this action in Florida state court, asserting claims of negligence, strict liability, and breach of implied warranty concerning an alleged pacemaker system failure. The matter was removed to the United States District Court for the Middle District of Florida pursuant to 28 U.S.C. §§ 1332(a) and 1441 as a diversity of citizenship case with an amount in controversy in excess of $50,000. The district court subsequently dismissed the implied warranty claim for failure to state a claim under Florida law. *See* App. 6a-7a.

On October 27, 1993, Medtronic moved for summary judgment on the ground that the FDCA preempted the remaining claims of negligence and strict liability. Although the district court initially denied the motion, App. 1d, it granted reconsideration because of the Eleventh Circuit's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994), which had affirmed the preemption of negligence and strict liability claims under the FDCA. On March 16, 1994, the district court entered judgment for Medtronic on the ground that respondents' claims are preempted. App. 1b.

C. The Court of Appeals Opinion

The Eleventh Circuit affirmed the preemption of respondents' claims to the extent that they involved allegations of failure to warn or defective manufacture but reversed to the extent that the claims related to device design. The court of appeals based its analysis primarily upon the FDCA express preemption provision, 21 U.S.C. § 360k(a), and a comparison between state and federal requirements governing the Model 4011 lead.

Citing this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Eleventh Circuit held that "common law actions are state requirements within the meaning of § 360k(a)." App. 11a. Specifically, the court of appeals held that respondents' claims would create state requirements by asking a jury to determine how a reasonable manufacturer should design, manufacture, and provide warnings for the pacemaker lead at issue. App. 25a, 30a, 32a.

The court below then relied upon the following FDA regulation interpreting section 360k(a) to limit the types of federal requirements that would preempt different or additional state requirements:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (1995), *quoted in part at* App. 16a. The Eleventh Circuit deferred to the FDA's interpretive regulation, because it held that it was a "reasonable" construction

that "avoids a host of problems raised by a literal reading of § 360k(a)," whereas a literal reading of the statute "would infer broad preemptive intent." App. 16a. In so holding, the court of appeals rejected Medtronic's argument that under *Cipollone* the analysis should be "governed entirely by the express language" of the Act. App. 14a (quoting *Cipollone*, 505 U.S. at 517).

The Eleventh Circuit also rejected respondents' claim that the FDA's interpretive regulation limited preemption to circumstances in which a federal requirement is so specific that it only applies to a single type of device. Holding that the FDA regulation "does not suggest that the requirements themselves must mention the particular device in question," the court of appeals concluded that "[o]ur preemption inquiry must ask whether 'specific requirements' apply to a device, not whether the requirements specify the device." App. 19a. In support of its interpretation, the court below noted that other circuits have held that federal requirements applicable to numerous device types preempt common law claims. App. 20a-21a. Nonetheless, the court of appeals concluded that "preemption-triggering requirements should, in some way, be 'restricted by nature' to a particular process, procedure, or device and should not be completely open-ended." App. 21a-22a (footnote omitted).

Based upon its limiting definition of the term "requirement," the court of appeals held that there were federal requirements that preempted respondents' claims to the extent that they involved allegations of failure to warn or defective manufacture. According to the court's analysis, the failure to warn claims were preempted by the federal prescription device labeling regulation, 21 C.F.R. § 801.109, which specifies warnings that must be included in the labeling of prescription devices such as the Model 4011 lead. App. 32a. The court of appeals premised preemption of the

manufacturing claims upon the FDA's good manufacturing practice regulations, 21 C.F.R. pt. 820, which establish federal quality assurance standards for manufacturing. App. 30a.

However, the Eleventh Circuit also held that respondents' claims relating to device design were not preempted, because the court could not identify any federal design requirement that met its definition of that term as used in section 360k(a). In so holding, the court concluded that the FDA's review and clearance of the device's design through the 510(k) process did not preempt the design claims. App. 28a-29a. The court suggested that there could be no express preemption of design claims unless there were substantive federal requirements that "set the standard" for the device's design. *See* App. 25a. Because the FDCA does not specify such design standards, the court held that the respondents' design claims were not expressly preempted under section 360k(a). App. 29a.[2] The Eleventh Circuit's holding therefore preserved state law claims from express and implied preemption even though the claims exposed a manufacturer to state law liability for marketing a device design affirmatively authorized under a complex federal regulatory scheme.

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[2] The court of appeals also concluded that respondents' claims were not subject to implied preemption, because it could not identify any actual conflict between federal and state law. App. 10a n.5.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS DECISION ESTABLISHES A DIRECT CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEALS

The Eleventh Circuit's decision establishes a mature conflict among the circuits concerning the scope of federal preemption under the FDCA. Recent decisions of the Third and Fourth Circuits now conflict with decisions of the Fifth and Eleventh Circuits on the identical question—whether the FDCA preempts design claims involving a Class III device cleared for marketing under the 510(k) process. In addition, the principles underlying the Eleventh Circuit's opinion conflict directly with the premises of decisions by the First, Second, Seventh, and Eighth Circuits upholding preemption of design claims in closely analogous cases. The decisions of these four circuits in turn conflict fundamentally with a recent decision of the Ninth Circuit.

By denying preemption of design claims involving a Class III 510(k) device, the Eleventh Circuit's decision conflicts directly with recent decisions of the Third and Fourth Circuits. In *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), the Fourth Circuit considered whether the FDCA preempts negligence and strict liability claims for defective design of a Class III 510(k) device. In contrast to the court below, the *Duvall* court held that the 510(k) process was itself a federal requirement that preempted common law claims, including design claims. *Id.* at 399-400. *Duvall* emphasized that through the 510(k) process, the FDA reviews design information and then authorizes marketing a device with the particular design submitted. *Id.* at 399. In addition, because the 510(k) process substantially restricts changes in device design following initial clearance, the Fourth Circuit concluded that "for all intents and purposes, [the manufac-

turer] is required to continue to design . . . the device as proposed in its original 510(k) Notification." *Id.* at 399-400. The Fourth Circuit then held that these federal requirements expressly preempted common law claims alleging design defect. *Id.* at 401.

Similarly, in *English v. Mentor Corp.*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995), the Third Circuit considered whether the FDCA expressly preempted state common law claims, including a negligent design claim, concerning a Class III 510(k) device.[3] The Third Circuit held that the 510(k) process was a federal "requirement" with preemptive effect within the meaning of section 360k(a). *Id.* at *15. The *English* court then concluded that the negligent design claim was expressly preempted, incorporating by reference the reasoning in two other Third Circuit cases that affirmed preemption of common law claims. *Id.* at *7, *19 (citing *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995)).

The Fifth Circuit has taken a position consistent with the conclusion of the Eleventh Circuit below, and therefore in direct conflict with the Third and Fourth Circuits, on the identical design claim issue. In *Feldt v. Mentor Corp.*, 61

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[3] Although the Third Circuit opinion did not specify which of these claims related to design, the district court opinion in *English* makes clear that the claims reviewed by the Third Circuit included "negligence in the design" of the device. *English v. Mentor Corp.*, No. 93-2725, 1994 U.S. Dist. LEXIS 7941, at *1 (E.D. Pa. June 10, 1994), *aff'd in part, rev'd in part*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995).

F.3d 431 (5th Cir. 1995), the Fifth Circuit denied preemption of design claims involving a Class III 510(k) device. Like the Eleventh Circuit, the *Feldt* court premised its holding upon a conclusion that there were no federal design requirements giving rise to preemption under the FDCA. *Id.* at 437-38. At the present time, therefore, decisions of the Fifth and Eleventh Circuits conflict squarely with decisions of the Third and Fourth Circuits.

The conflict among the four circuits concerning the preemption of design claims also is mirrored in the lower federal and state courts, with some upholding preemption of design claims involving Class III 510(k) devices[4] and others denying preemption under the same circumstances.[5] In addition, the holding of one state supreme court cannot be reconciled with the holdings of the Third and Fourth Circuits. In *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992), the Supreme Court of Hawaii denied preemption of a common law claim involving a Class III 510(k) device on the ground that the 510(k) process does not impose preemptive federal requirements within the meaning of the FDCA. *Id.* at 1282. Even though the claim at issue was not explicitly described as a design claim, *Larsen* is consistent with the holdings of the Fifth and Eleventh Circuits, and inconsistent

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[4] *See, e.g., Caraballo v. Intermedics, Inc.*, 886 F. Supp. 974 (D.P.R. 1995); *Bokis v. American Medical Sys., Inc.*, 875 F. Supp. 748 (W.D. Okla. 1995); *Bollier v. Medtronic, Inc.*, No. H-92-2439, 1993 WL 734843 (S.D. Tex. Oct. 28, 1993).

[5] *See, e.g., Fender v. Medtronic, Inc.*, 887 F. Supp. 1326 (E.D. Cal. 1995) (dicta); *Sylvester v. Mentor Corp.*, No. 95-67, 1995 La. App. LEXIS 2490 (La. Ct. App. Sept. 20, 1995); *Fogal v. Steinfeld*, 620 N.Y.S.2d 875 (N.Y. Sup. Ct. 1994).

with the holdings of the Third and Fourth Circuits, regarding design claims.

Although the conflict among the Third, Fourth, Fifth, and Eleventh Circuits is direct, substantial, and irreconcilable, several other recent cases enhance the magnitude of the conflict over the scope of preemption under section 360k. The contradictions among the lower court holdings have spread to four other circuits that have not yet squarely decided whether design claims involving Class III 510(k) devices are preempted but have faced closely related issues. For example, the Eighth Circuit has denied preemption of design claims involving a Class II 510(k) device. *See National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 997 (8th Cir. 1994). Because the regulations governing the 510(k) process do not distinguish between Class II and Class III devices, the Eighth Circuit's opinion adds further confusion to the lower courts' jurisprudence concerning the design claim issue presented in this case.

Furthermore, the First, Seventh, and Eighth Circuits have affirmed preemption of design claims involving Class III devices approved for marketing through the PMA process.[6] Similarly, the Second and Seventh Circuits have affirmed preemption of design claims involving Class III devices cleared for clinical experimental use through the IDE proc-

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[6] *See King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Mitchell v. Collagen Corp.*, No. 94-3946, 1995 U.S. App. LEXIS 27709 (7th Cir. Oct. 2, 1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995).

ess.[7] The premises of these decisions conflict directly with the principles underlying the Eleventh Circuit's decision below and the Fifth Circuit's decision in *Feldt*. There is no relevant distinction between the federal design requirements imposed by the PMA process (held preemptive by the First, Seventh and Eighth Circuits), the IDE process (held preemptive by the Second and Seventh Circuits), and the 510(k) process implicated by the decisions of the Fifth and Eleventh Circuits.

Under the FDCA, the manufacturer, not the FDA, proposes the initial design of devices, regardless of whether they are cleared for distribution through the 510(k), PMA, or IDE processes.[8] Following careful individualized review, the FDA clears devices for distribution on a case by case basis with the particular design submitted, regardless of which of the three clearance processes is used.[9] Manufacturers are then prohibited from changing the FDA-authorized design of 510(k), PMA, and IDE devices in a way that could affect safety or effectiveness significantly without additional FDA clearance.[10] None of the three processes establishes preexisting substantive design standards. By concluding that federal design standards are prerequisite for preemption, the

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[7] *See Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Slater v. Optical Radiation Corp.*, 961 F.3d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992).

[8] *See* 21 C.F.R. §§ 807.87 (510(k)); 814.20 (PMA); 812.20, 812.25, 813.20, 813.25 (IDE).

[9] *See id.* § 807.100 (510(k)); 21 U.S.C. § 360e(d)(1)(A) (PMA); 21 C.F.R. § 812.30 (IDE).

[10] *See* 21 C.F.R. §§ 807.81(a)(3)(i) (510(k)); 814.39(a) (PMA); 812.30(b)(1), 812.35(a)(1), 813.35(a)(9), 813.39(b)(1) (IDE).

Eleventh Circuit has taken a position inconsistent with the decisions of the First, Second, Seventh, and Eighth Circuits cited above, which have upheld preemption of design claims in the absence of such standards.[11]

The widespread and recurring conflicts described above call for prompt resolution by this Court. Because the scope of preemption varies among the circuits, national medical device manufacturers such as Medtronic, which do business in all fifty states, confront dramatic differences in liability exposure from state to state for the identical product design. In those circuits that have preserved liability for design claims by limiting preemption, variances among jury verdicts add further unpredictability for manufacturers that design new devices. This confusing and disjointed pattern of liability exposure interrupts the rational and efficient development, production, and sale of life-saving medical devices. Indeed, the current state of the law—in which manufacturers may either be insulated from, or exposed to, liability solely on the basis of the particular circuit in which a suit is filed—undermines the very purpose of the FDCA preemption provision. Congress enacted that provision to enhance uniformity of regulatory requirements so that the regulatory structure would not stifle technological innovations of vital importance to the public's health.

Until this Court resolves the conflict among the circuits, this burden on innovation will persist. This Court has never

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[11] These opinions of the First, Second, Seventh, and Eighth Circuits in turn conflict with the premises of a recent Ninth Circuit decision holding that the FDCA's express preemption provision does not encompass preemption of any common law claims. *See Kennedy v. Collagen Corp.*, No. 94-15197, 1995 WL 606511 (9th Cir. Oct. 17, 1995).

construed the express preemption provision of the FDCA, and it therefore has not yet provided a basis for the lower courts to resolve the conflict on their own. In addition, because the lower court opinions are premised upon the construction of a particular statutory provision that shows no sign of being amended in the near future, there is no reason to believe that additional cases in the foreseeable future will lead to a unification of the doctrine. Without Supreme Court guidance, the different circuits have felt free to disregard the opinions of other circuits. Each has forged its own construction of the statute, and there is no basis for concluding that they will reverse course. Thus, the conflict among the circuits is not likely to be resolved unless this Court grants review and establishes the uniformity that is so badly needed. Because the question of the scope of federal preemption under the FDCA has been litigated extensively in numerous lower courts, it is ripe for review in this Court.[12]

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[12] The various circuits have decided eleven other cases construing the FDCA preemption provision in addition to the eleven decisions discussed above. *See Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *LaMontagne v. E.I. du Pont de Nemours & Co.*, 41 F.3d 846 (2d Cir. 1994), *aff'g* 834 F. Supp. 576 (D. Conn. 1993); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Jacobs v. E.I. du Pont de Nemours & Co.*, No. 93-4144, 1995 U.S. App. LEXIS 29436 (6th Cir. Oct. 19, 1995); *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994).

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

A decision of this Court on the question presented would have widespread and profound effects upon the medical device industry and the consuming public, because it would define the scope of potential liability for the vast majority of the most critical medical devices. The Court certainly would resolve the scope of preemption concerning Class III 510(k) devices such as the Model 4011 lead, a question that is being litigated repetitively throughout the country with hopelessly inconsistent results. This matter is of critical importance because, as Congress noted in 1990, "over 80 percent of the devices that are potentially the most dangerous (Class III), enter the market" through the 510(k) process. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307. Class III 510(k) devices—which the FDCA defines as those purporting to be life-sustaining or life-supporting, or presenting a potentially unreasonable risk of illness or injury[13]—span the entire spectrum of critical medical technologies, from artificial hip joints to kidney dialysis systems to certain breast implants.[14] This Court should grant the petition for certiorari to resolve the scope of preemption concerning common law liability governing this vitally important category of medical products.

The present case is the proper vehicle for defining the scope of preemption for Class III 510(k) devices, because it clearly presents the one "hard issue" that has most divided

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[13] *See* 21 U.S.C. § 360c(a)(1)(C) (1994).

[14] *See* 21 C.F.R. §§ 888.3330, 876.5860, 878.3530 (1995).

the lower courts—whether common law claims involving the design of these devices are preserved or entirely foreclosed. As the numerous decisions cited above make clear, state law claims in medical device cases typically fall into one of three categories: labeling, manufacturing, or design. Although every circuit that has reviewed cases involving Class III 510(k) devices (including the court below) has affirmed preemption of claims relating to labeling or manufacturing,[15] the extension of preemption to design claims has proved more controversial.

The courts have divided over the design claim issue, because the federal requirements governing design under the 510(k) process differ from those governing labeling and manufacturing. Under the FDCA, the FDA has promulgated regulations establishing specific substantive standards for labeling and manufacturing independent of the requirements of the 510(k) process itself. The lower courts have relied on these regulations to a greater or lesser extent as the premise for upholding preemption of labeling and manufacturing

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[15] *See Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (labeling and manufacturing claims preempted); *English v. Mentor Corp.*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995) (labeling and manufacturing claims preempted, with the exception of express warranty claims); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995) (labeling and manufacturing claims preempted, with the exception of certain express warranty claims); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995) (labeling claims preempted); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995) (App. 1a) (labeling and manufacturing claims preempted). Although *English* and *Duvall* established certain exceptions to preemption for express warranty claims, this Court recently has denied review of that issue. *See* Petition for Certiorari at i, *Shiley, Inc. v. Michael*, No. 94-1971, *cert. denied*, 116 S. Ct. 67 (Oct. 2, 1995).

claims.[16] In contrast, the primary federal requirements governing design of 510(k) devices are imposed through the 510(k) process itself rather than through particular pre-existing design standards. Through this complex regulatory process, the FDA reviews proposed designs, authorizes them for marketing, and prohibits significant changes in design without further authorization. This case therefore squarely presents the question whether the 510(k) process itself preempts common law claims (thereby foreclosing liability entirely) or leaves manufacturers exposed to viable lawsuits based upon device design.

The present case provides this Court with the best opportunity it has yet had to resolve the scope of FDCA preemption. This case is a "hard" case, because it involves both the agency review process and the particular category of common law claims that have most divided the lower courts. It is a very significant case, because a decision would affect over 80 percent of the most critical medical devices that enter the market. This Court should grant the petition in order to establish uniformity and certainty concerning the scope of liability for these medical products of vital importance to the public's health.

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[16] *See English*, 1995 U.S. App. LEXIS 27670, at *19; *Duvall*, 65 F.3d at 399; *Feldt*, 61 F.3d at 436; *Lohr*, App. 14a-18a.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

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November 13, 1995

APPENDICES

Lora Lohr, Michael Lohr, Her Husband, Plaintiffs-Appellants, v. Medtronic, Inc., a Foreign Corporation, Defendant-Appellee.	No. 94-2516

United States Court of Appeals,
Eleventh Circuit.

July 3, 1995.

Daniel C. Shaughnessy, Cowles & Shaughnessy, P.A., Robert F. Spohrer, Spohrer, Wilner & Maxwell, P.A., Jacksonville, FL, Brian Wolfman, Public Citizen Litigation Group, Washington, DC, for appellants.

Dennis P. Waggoner, Hill, Ward & Henderson, P.A., Tampa, FL, Marcus R. Magnuson, Medtronic, Inc., Minneapolis, MN, Daniel G. Jarcho, McKenna & Cuneo, Washington, DC, for appellee.

Appeal from the United States District Court for the Middle District of Florida.

Before Black and Barkett, Circuit Judges, and Roney, Senior Circuit Judge.

Black, Circuit Judge:

In this case we must decide whether the Medical Device Amendments of 1976 (MDA or Act), 21 U.S.C.A. §§ 360c-360l (West Supp.1994) preempt Appellants' state law negligent design, negligent manufacture, failure to warn, and strict liability claims against the manufacturer of an allegedly de-

fective pacemaker. The district court found that they did and dismissed the entire action. We hold that Appellants' negligent manufacture and failure to warn claims are preempted and affirm their dismissal. We also hold that Appellants' negligent design and strict liability claims are not preempted and therefore reverse their dismissal.

I. BACKGROUND

Because an understanding of the MDA's regulatory scheme is necessary to resolve the question of preemption, we begin with a brief outline of the Act.

A. The Regulatory Scheme

The market for medical devices was largely unregulated at the national level until the MDA's passage in 1976. With the MDA, Congress gave the federal Food and Drug Administration (FDA) comprehensive jurisdiction over all "devices intended for human use." 21 U.S.C.A. § 360c(a)(1). The text of the MDA reveals two competing congressional purposes relevant to this case:[1] (1) the MDA protects the public from unnecessary illness or injury by subjecting medical devices to a regulatory scheme designed to ensure that the devices are safe and effective, *see, e.g.*, 21 U.S.C.A. §§ 360c(a)(1)(A)(i); 360c(a)(1)(B); 360e(d)(2); and (2) the

[1] Nothing we say here should be interpreted as identifying the exclusive motives of Congress in passing the Act. Courts must be mindful of the fact that legislative acts reflect many competing interests and should not allow vague notions about a statute's overall purpose to overcome its plain text. *Mertens v. Hewitt Associates*, — U.S. ——, ——, 113 S.Ct. 2063, 2071, 124 L.Ed.2d 161 (1993).

MDA protects the public by encouraging the development and marketing of medical devices by crafting a nationally uniform regulatory scheme that prevents overregulation and thus ensures that development can be economically feasible, *see, e.g.*, 21 U.S.C.A. §§ 360j(g)(1); 360k(a).

These twin purposes are confirmed by the legislative history of the Act. For example, the House Report on the Act states:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

H.R.Rep. No. 853, 94th Cong., 2d Sess. 10 (1976). Legislative history from the Senate reflects the same balancing of interests. *See* S.Rep. No. 33, 94th Cong., 1st Sess. 5, 12 (1975). The need to balance public safety with continued development was reiterated when Congress amended the MDA in 1990.

> Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices.

S.Rep. No. 513, 101st Cong., 2d Sess. 13 (1990). The MDA thus reflects the intent of Congress to scrutinize the medical device industry to a greater extent without stifling innovation and development.

All medical devices regulated by the MDA fall into three statutory categories. Class I devices are those which pose little threat to the safety of the consuming public. These devices, including everything from tongue depressors to acoustic chambers, are subject only to the Act's generally applicable regulations. *See* 21 U.S.C.A. § 360c(a)(1)(A). Class II devices are those which pose enough of a safety hazard to require regulation beyond the general controls applicable to Class I devices. Class II devices, like tampons and oxygen masks, are consequently subject to device-specific special controls. *See* 21 U.S.C.A. § 360c(a)(1)(B).

Class III devices are those that the FDA determines are too unproven to be rendered safe by general controls or present a potential for unreasonable risk of illness or injury. Almost all life-sustaining medical devices, like pacemakers, are classified as Class III devices. In addition to the Act's general regulations and, in some instances, device-specific controls, Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace. *See* 21 U.S.C.A. § 360c(a)(1)(C). The premarket approval process is a vigorous one, requiring the applicant to present the FDA with "all information" known or reasonably knowable about the device, including detailed information about the design, manufacture, uses, and labeling of the device. 21 U.S.C.A. § 360e(c)(1).

While the MDA contemplates that most Class III devices will reach the market through the PMA process, there are important exceptions. First, the MDA grandfathered into the market all devices introduced before May 28, 1976—the effective date of the Act. 21 U.S.C.A. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1994). Second, the MDA contains an investigational device exemption (IDE) for new devices under clinical investigation to determine their safety or effectiveness. 21 C.F.R. § 812.3(g). *See* 21 U.S.C.A. § 360j(g). In

order to foster the development of useful devices, IDE procedures allow manufacturers to begin limited marketing of new devices without undergoing the rigorous PMA process. 21 U.S.C.A. § 360j(g)(1).

Finally, a Class III device may reach the market without undergoing the PMA procedures if the device is found to be the "substantial equivalent" of an already-marketed device, including a device grandfathered into the market. 21 U.S.C.A. § 360e(b)(1)(B). For a device to qualify as the substantial equivalent of one which is already being marketed, the FDA must determine that the new device has the same intended use as the predicate device and either the same technological characteristics or the same safety and effectiveness as the predicate device. 21 U.S.C.A. § 360c(i)(1)(A). Every device entering the market as a substantial equivalent is subject to a premarket notification process (510(k) process) which allows the FDA to classify the device and make its substantial equivalence finding. 21 U.S.C.A. §§ 360(k); 360c(f)(1).

B. Facts[2]

This case arises from the failure of a pacemaker manufactured by Appellee Medtronic, Inc. The pacemaker in question, the Model 8403 Activitrax (Activitrax), is a Class III device under the MDA. 21 C.F.R. § 870.3610. The Activitrax has never been subject to the PMA process. *See* 21 C.F.R. § 870.3610(c).

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[2] For purposes of this appeal, we accept the facts in Appellants' complaint as true.

Appellant Lora Lohr was implanted with an Activitrax pacemaker in 1987. The pacemaker failed in 1990, forcing Ms. Lohr to endure emergency surgery to replace the Activitrax. According to Ms. Lohr's treating physician, the failure was caused by a defect in the pacemaker "lead"—the wire carrying electrical impulses from the pacemaker to the patient's heart tissues.

The Activitrax lead component, the Model 4011, is manufactured by Appellee as part of its pacemaker system. The FDA permitted marketing of the Model 4011 in 1982 after finding that it was the substantial equivalent of a device introduced prior to the effective date of the MDA. In other words, the Model 4011 entered the market through the 510(k) process as the substantial equivalent of a device grandfathered into the Act.

C. Procedural History

Appellants Lora and Michael Lohr originally brought this action in a Florida court, but Appellee removed the case to the Middle District of Florida based on diversity of citizenship. In their complaint, Appellants seek damages for injuries Lora Lohr allegedly sustained as a result of the Activitrax's failure and for Michael Lohr's alleged loss of consortium. The complaint contains four theories of liability: (1) negligent design; (2) negligent manufacture; (3) negligent failure to warn; and (4) strict liability in tort.[3]

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[3] The original complaint contained a breach of warranty claim which was dismissed for failure to state a claim under Florida law and is not at issue in this appeal.

Shortly after removing the case, Appellee moved for summary judgment, asserting that Appellants' claims were preempted by the MDA. The district court denied the motion in December 1993, but reconsidered its decision in light of this Court's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). Upon reconsideration, the district court granted Appellee's motion for summary judgment, interpreting Duncan as preempting all state law claims for negligence and strict liability. This appeal follows.[4]

II. DISCUSSION

The sole issue on appeal is whether the district court erred in holding that the MDA preempts all common law tort claims against a Class III device which entered the market

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[4] Prior to oral argument, Appellants sought to supplement their submissions to the Court with an additional brief. A similar request from Appellee and a request to reply to Appellee's supplemental brief inevitably followed. We carried these motions with the case. Appellants' supplemental brief appears to be a vehicle for bringing before the Court the FDA's amicus brief in *Talbott v. C.R. Bard, Inc.*, 1st Cir. No. 94-1951, a pending First Circuit case concerning preemption under the MDA. Litigating positions of an agency, as distinct from the agency's regulations, rulings, and practice, are entitled to no deference. *Martin v. OSHRC*, 499 U.S. 144, 154-56, 111 S.Ct. 1171, 1178, 113 L.Ed.2d 117 (1991); *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 210-14, 109 S.Ct. 468, 473-74, 102 L.Ed.2d 493 (1988); *Alabama Dry Dock and Shipbuilding Corp. v. Sowell*, 933 F.2d 1561, 1563 (11th Cir.1991). Consequently, Appellants' supplemental brief would not aid the Court in resolving this case and we deny the motion to supplement. Appellee's motion to supplement and Appellants' supplemental reply are premised on consideration of Appellants' first supplemental brief, and our decision to reject that brief precludes the other submissions.

through the 510(k) process as the substantial equivalent of a grandfathered device.

A. Standard of Review

Statutory interpretation presents a question of law over which we exercise de novo review. *Barnett Bank of Marion County, N.A. v. Gallagher*, 43 F.3d 631, 633 (11th Cir.1995). We review an administrative agency's statutory interpretation de novo, but defer to an agency's interpretation if it is reasonable. *Asencio v. I.N.S.*, 37 F.3d 614, 616 (11th Cir.1994).

B. Preemption Under the MDA

The Constitution makes the laws of the United States "the supreme Law of the Land; ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding," U.S. Const. art. VI, cl. 2, and when federal and state laws conflict, the latter must give way, *CSX Transp., Inc. v. Easterwood*, — U.S. ——, ——, 113 S.Ct. 1732, 1737, 123 L.Ed.2d 387 (1993). Whether a federal statute preempts state law is a question of congressional intent. *Hawaiian Airlines, Inc. v. Norris*, — U.S. ——, ——, 114 S.Ct. 2239, 2243, 129 L.Ed.2d 203 (1994); *Forbus v. Sears Roebuck & Co.*, 30 F.3d 1402, 1405 (11th Cir.1994), *cert. denied*, — U.S. ——, 115 S.Ct. 906, 130 L.Ed.2d 788 (1995). Congressional enactment of a provision defining the preemptive scope of a statute implies that it intended to limit the preemptive scope of the statute to the express terms of the preemption provision. *Freightliner Corp. v. Myrick*, — U.S. ——, ——, 115 S.Ct. 1483, 1488, 131 L.Ed.2d 385 (1995); *Cipollone v. Liggett Group, Inc.*, — U.S. ——, ——, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992). In the absence of a "general, inherent conflict" between the state and federal law, review is limited to the express terms of the pre-

emption provision. *Freightliner*, — U.S. at ——, 115 S.Ct. at 1488 (quoting *Cipollone*, — U.S. at ——, 112 S.Ct. at 2618).

In determining the preemptive scope of the express language, however, several presumptions guide our analysis. First, preemption is appropriate only if it is the clear and manifest purpose of Congress. *Department of Revenue of Or. v. ACF Industries, Inc.*, — U.S. ——, ——, 114 S.Ct. 843, 851, 127 L.Ed.2d 165 (1994); *CSX*, — U.S. at ——, 113 S.Ct. at 1737; *United States v. Lot 5, Fox Grove, Alachua County, Fla.*, 23 F.3d 359, 361 (11th Cir.1994), *cert. denied*, — U.S. ——, 115 S.Ct. 722, 130 L.Ed.2d 627 (1995). Second, preemption of actions within the traditional police powers of a state "should not be lightly inferred." *Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2243 (quoting *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 21, 107 S.Ct. 2211, 2222, 96 L.Ed.2d 1 (1987)). Finally, there is a presumption against preemption if it would deny a party all judicial remedies. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251-52, 104 S.Ct. 615, 623, 78 L.Ed.2d 443 (1984); *Michael v. Shiley*, Inc., 46 F.3d 1316, 1326 (3rd Cir.1995). Although the presumptions against preemption cannot drive our analysis and must yield to a clear expression of congressional intent, in a close case the presumptions tip our statutory interpretation against preemption. *See Cipollone*, — U.S. at ——, 112 S.Ct. at 2618; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-85, 112 S.Ct. 2031, 2037, 119 L.Ed.2d 157 (1992).

Preemption under the MDA is governed by the Act's preemption provision,[5] which states:

> Except as provided in subsection (b) of this section [delineating an exemption procedure not relevant to this case], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a). To determine whether Appellants' claims are preempted by the MDA, we must compare the "State . . . requirement[s]" under which the suit was brought with MDA-imposed requirements. Before comparing Appellants' claims with the requirements imposed on the Activitrax by the MDA, however, we must address two threshold questions: (1) what constitutes a "State . . . requirement" and (2) what constitutes a "requirement" under the MDA. 21 U.S.C.A. § 360k(a).

[5] Both parties accept the preemption provision as controlling. Although the Supreme Court recently explained that implied preemption is sometimes appropriate despite the existence of an express preemption provision, *see Freightliner*, — U.S. at ——, 115 S.Ct. at 1487-88, we doubt that this is such a case. First, it does not seem impossible for a manufacturer to comply with the MDA's requirements and any additional requirements which Appellants' suit might add. *See id.* — U.S. at ——, 115 S.Ct. at 1488. Second, it does not appear that Appellants' suit would frustrate "the full purposes and objectives of Congress." *Id.*

1. State Requirement.

To determine what § 360k(a) means by a "State . . . requirement different from, or in addition to" MDA requirements, we must consider whether Congress intended to include state common law actions.[6] Were we writing on a clean slate, this might present a difficult question, but we do not write on a clean slate. In *Duncan v. Iolab Corp.*, 12 F.3d 194, this Court adopted the Seventh Circuit's reasoning in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, — U.S. ——, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992), and held that the MDA preempted a plaintiff's negligence, strict liability, and breach of implied warranty claims. Thus, the law of this Circuit is that the phrase "State . . . requirement" in § 360k(a) includes state common law tort actions. *See also Cipollone*, — U.S. at ——, 112 S.Ct. at 2620 ("The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law") (quoting 15 U.S.C. § 1334(b)). Every circuit to consider the question agrees that common law actions are state requirements within the meaning of § 360k(a).[7]

[6] Appellants' initial brief did not appear to dispute whether their claims were based on state requirements within the meaning of § 360k(a). Their reply brief, however, appears to dispute the issue in this appeal.

[7] *See Mendes v. Medtronic, Inc.*,, 18 F.3d 13, 16 (1st Cir.1994); *Michael*, 46 F.3d at 1323 (3rd Cir.); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 304 (5th Cir.1995); *Slater*, 961 F.2d at 1332-33 (7th Cir.); *Martello*

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The existence of a savings clause within the MDA cannot alter this conclusion. The savings clause states that "[c]ompliance with an order [under the MDA] shall not relieve any person from liability under Federal or State law." 21 U.S.C.A. § 360h(d). While the savings clause almost certainly prohibits a holding that the MDA preempts all state law liability, our interpretation of § 360k(a) does not preclude all liability. Further, nothing in the savings clause suggests that some tort liability, as opposed to other types of liability, must be preserved. Interpreting the savings clause to preserve non-tort liability, such as contract liability, is not only permissible, but also comports with the Supreme Court's interpretation of a savings clause in a recent preemption case. *See American Airlines, Inc. v. Wolens*, — U.S. ——, ——, 115 S.Ct. 817, 826, 130 L.Ed.2d 715 (1995) (holding that the Airline Deregulation Act preempts claims under the Illinois Consumer Fraud and Deceptive Business Practices Act but does not preempt state breach of contract actions). Moreover, where the preemptive intent of Congress is clear, a general savings clause cannot supersede the specific preemption provision. *Morales*, 504 U.S. at 383-85, 112 S.Ct. at 2037. In short, as long as we interpret § 360k(a) as permitting some state law liability, the MDA's savings clause simply begs the question of what liability it preserves.

Appellants' reply brief suggests that their negligent manufacturing and failure to warn claims are exempt from preemption under § 360k(a) because the claims may dem-

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v. CIBA Vision Corp., 42 F.3d 1167, 1168 (8th Cir.1994); *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir.1995).

onstrate a violation of the MDA's own requirements and, therefore, do not constitute state requirements "different from, or in addition to" the Act's requirements. While we ordinarily do not address arguments first raised in a reply brief, *Allstate Ins. Co. v. Swann*, 27 F.3d 1539, 1542 (11th Cir.1994), we will exercise discretion to reach this question because the law in this Circuit forecloses Appellants' argument.[8]

Papas v. Upjohn Co., 985 F.2d 516 (11th Cir.), *cert. denied*, — U.S. ——, 114 S.Ct. 300, 126 L.Ed.2d 248 (1993), considered the scope of preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 7 U.S.C.A. §§ 136-136y. In *Papas*, the plaintiffs, like Appellants in this case, argued against preemption by claiming that their common law action would show a violation of the EPA's own FIFRA labeling standards. Therefore, the plaintiffs claimed that their suit was not a "requirement . . . in addition to or different from" FIFRA's labeling requirements. *Papas*, 985 F.2d at 518-19 (quoting 7 U.S.C.A. § 136v). We rejected the argument, noting that "it is for [the agency], not a jury, to determine whether labelling and packaging information is incomplete or inaccurate, and if so what label changes, if any, should be made." *Id.* at 519. We believe *Papas* controls here and hold that preemption under the MDA cannot be defeated by a common-law suit alleging a

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[8] We assume, arguendo, that Florida common law would recognize an action whose standard of care is defined by the standards of the MDA and that Appellants' complaint may be read broadly enough to encompass such an action.

violation of the statutory standards. Every circuit court decision addressing this issue under the MDA agrees.[9]

2. Requirements Under the MDA.

a. The FDA's Preemption Regulations.

Where the plain meaning of the express terms of a statute is unclear, we may defer to a reasonable interpretation adopted by the agency charged with enforcing the statute. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44, 104 S.Ct. 2778, 2782, 81 L.Ed.2d 694 (1984). Appellants insist that the meaning of "requirements" as used in § 360k(a) is unclear and that we should therefore defer to the FDA regulations clarifying the meaning of "requirements."[10]

Appellee responds that under the express preemption rule enunciated in *Cipollone v. Liggett Group, Inc.*, our analysis should be "governed entirely by the express language" of the Act. *Cipollone*, — U.S. at ——, 112 S.Ct. at 2618. Alternatively, Appellee argues that the FDA's regulations are contrary to the clear intent of Congress and, therefore, are not entitled to deference. We disagree.

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[9] *Michael*, 46 F.3d at 1328-29; *Reeves*, 44 F.3d at 307; *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n. 2 (8th Cir.1994); *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.) (opinion of Aldrich and Campbell, JJ.), *cert. denied*, — U.S. ——, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993).

[10] Congress empowered the FDA to promulgate regulations to enforce the MDA. *See* 21 U.S.C.A. § 371(a).

Cipollone did not prohibit reliance on an agency's preemption regulations. While the opinion speaks only of "the express language" of the statutes, neither of the statutes examined in *Cipollone* had regulations interpreting its preemptive scope and nothing in the opinion indicates that the issue of preemption regulations was ever raised or considered. Appellee's argument thus asks us to find a sub silentio holding in *Cipollone*, something which courts are reluctant to do. *See Federal Election Com'n v. NRA Political Victory Fund*, — U.S. ——, ——, 115 S.Ct. 537, 542, 130 L.Ed.2d 439 (1994). Moreover, the Supreme Court has deferred to FDA preemption regulations in the past, *see Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-14, 105 S.Ct. 2371, 2375-76, 85 L.Ed.2d 714 (1985), and has examined another agency's preemption practices in at least one post-*Cipollone* case, *see Wolens*, — U.S. at ——, 115 S.Ct. at 825 (discussing the Department of Transportation's interpretation of its authority to displace courts in air carrier contract disputes). We are therefore unable to conclude that *Cipollone* created an express preemption rule which forecloses our examination of the FDA's regulations.

The principles guiding deference to an agency's interpretation of a statute are well established. First we must ask whether Congress has spoken directly to the precise question. *NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, — U.S. ——, ——, 115 S.Ct. 810, 813, 130 L.Ed.2d 740 (1995); *Chevron*, 467 U.S. at 841-43, 104 S.Ct. at 2781. If the statute does directly address the precise question, an agency interpretation to the contrary is entitled to no deference; if not, the Court must inquire into whether the agency's interpretation is reasonable. *NationsBank*, — U.S. at ——, 115 S.Ct. at 813-14; *Chevron*, 467 U.S. at 843-44, 104 S.Ct. at 2782. We defer to the agency's interpretation unless it is

"arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 844, 104 S.Ct. at 2782.

Congress's choice of the word "requirement" in § 360k(a)(1), does not speak directly to the precise issue of whether Appellants' state common law tort claims are preempted by the MDA. As used in § 360k(a), a "requirement" refers to a legal obligation, *see Brown v. Gardner*, — U.S. ——, ——, 115 S.Ct. 552, 555, 130 L.Ed.2d 462 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context") and the corresponding definition is "something called for or demanded," Webster's New International Dictionary 1929 (3d ed. 1976). *See Asgrow Seed Co. v. Winterboer*, — U.S. ——, ——, 115 S.Ct. 788, 793, 130 L.Ed.2d 682 (1995) (stating that undefined statutory terms should be given their ordinary meaning). Even using this ordinary meaning, the scope of the word "requirement" is ambiguous and consideration of the FDA's interpretation is appropriate.

In defining the scope of § 360k(a), the FDA has indicated that:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . .

21 C.F.R. § 808.1(d) (emphasis added). We believe that this narrowing of the meaning of "requirement[s]" applicable . . . to the device" to "specific counterpart regulations" or "specific requirements applicable to a particular device" is reasonable because it avoids a host of problems raised by a literal reading of § 360k(a). First, an expansive reading of § 360k(a) would infer broad preemptive intent in the face of well-settled presumptions against such a construction. *See, e.g., ACF Industries*, — U.S. at ——, 114 S.Ct. at 851. Second, the broadest construction of § 360k(a) would call into question almost all state law liability pertaining to MDA-regulated manufacturers. Such an interpretation would render the MDA's savings clause, 21 U.S.C.A. § 360h(d), meaningless, violating a cardinal rule of statutory construction which avoids interpretations which render a statutory provision superfluous, *see Ratzlaf v. United States*, — U.S. ——, ——, 114 S.Ct. 655, 659, 126 L.Ed.2d 615 (1994). Third, although a state PMA requirement would logically be preempted by a literal reading of § 360k(a), the Act's legislative history suggests that such practices should not be preempted. H.R.Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976).[11]

Because Congress left open the question of what MDA "requirements" preempt competing state requirements, the FDA's addition of the word "specific" is a reasonable interpretation of the statute. By clarifying the statutory term "requirement" to mean "specific requirements," the FDA's preemption regulation stayed within the zone of reasonableness required of agency interpretations. *See Chevron*, 467 U.S. at 843-44, 104 S.Ct. at 2782-83. Finally, we note that every court decision which the parties have brought to our

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[11] The House Report cited California's premarket clearance program with approval as an example of practices which the FDA should exempt from preemption under § 360k(b). H.R.Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976). Nevertheless, we believe the statement is relevant to our interpretation of § 360k(a) by demonstrating that Congress had no desire to completely occupy the field of medical device regulation.

attention either explicitly[12] or implicitly[13] regards the preemption regulations as valid. We hold that the FDA's preemption regulations are a reasonable interpretation of § 360k(a) entitled to deference by the Court.

b. MDA Specific Requirements.

Although the FDA's clarification of § 360k(a) is helpful, we must still struggle with defining what "specific requirements" under the MDA trigger preemption. *See* 21 C.F.R. § 808.1(d). Appellants interpret the regulations to mean that in this case preemption is proper "only if there are federal requirements imposed specifically upon manufacturers of pacemakers regarding" design, manufacture, or warnings. In other words, Appellants take the position that only MDA regulations which state that "a pacemaker manufacturer must do . . ." can constitute "specific requirements" triggering preemption. Appellees, on the other hand, argue that the regulations cannot be interpreted to require device specificity.

A careful reading of the FDA's MDA preemption regulations does not support the device-specific interpretation Appellants seek to impose. Significantly, the regulations allow preemption "when [1] the Food and Drug Administration has established specific counterpart regula-

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[12] *See, e.g., Martello*, 42 F.3d at 1168; *King*, 983 F.2d at 1134; *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273, 1281 (Hawaii 1992); *Ginochio v. Surgikos, Inc.*, 864 F.Supp. 948, 952 (N.D.Cal.1994).

[13] *See, e.g., Michael*, 46 F.3d at 1324; *Anguiano*, 44 F.3d at 809; *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543-44 (3rd Cir.), *cert. denied*, — U.S. ——, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994); *Mendes*, 18 F.3d at 16; *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 n.8 (5th Cir.), *cert. denied*, — U.S. ——, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993).

tions or [2] there are other specific requirements applicable to a particular device under the act[.]" *Id.* (emphasis supplied). The word "or" in the regulation indicates that the FDA intended the two conditions for preemption to be alternatives so that the existence of either condition triggers preemption. *See Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2245. While the first condition, the existence of "specific counterpart regulations," might be read to require device specificity, the second condition cannot.

The most natural reading of the FDA's "specific requirements" language requires specificity in the nature of the requirements, not in their applicability to designated devices. The "applicable to a particular device" language, mirroring the statute, requires a court to ask whether the requirements in question apply to the device in question. *See* 21 U.S.C.A. § 360k(a); 21 C.F.R. § 808.1(d). That language does not suggest that the requirements themselves must mention the particular device in question. Our preemption inquiry must ask whether "specific requirements" apply to a device, not whether the requirements specify the device.

Construing the FDA's preemption regulations to require device specificity also contradicts the structure of the Act. Under the MDA, Class III devices are subject to the highest level of scrutiny through the PMA process.[14] *See* 21

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[14] The comparative costs of market entry under the MDA supports the conclusion that the PMA process presents the highest obstacle. While the average price-range of market entry through the premarket notification 510(k) procedure is $50 to $2,000, the equivalent range for devices undergoing the PMA process is $111,000 to $828,000. Robert B. Leflar, Public Accountability and Medical Device Regulation, 2 Harv.J.L. & Tech. 1, 47 (1989).

U.S.C.A. § 360c(a)(1)(C). *Accord Martello*, 42 F.3d at 1168; *Stamps*, 984 F.2d at 1419. Yet the PMA procedure's "requirements" under the MDA are not device-specific. Instead, the PMA process requires manufacturers to submit to an approval process standardized for all Class III devices. *See, e.g.*, 21 U.S.C.A. § 360e(c)-(d); 21 C.F.R. §§ 814.1-814.45. It would be anomalous for the MDA to preempt certain claims which conflict with device-specific requirements placed on Class II devices, *see National Bank*, 38 F.3d at 990; *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir.1989), but not preempt claims against devices subject to the MDA's most rigorous, albeit non-device-specific, procedures.[15] Thus, the overall structure of the MDA supports interpreting the FDA's preemption regulations as not requiring device specificity.

Finally, a device-specific requirement is contrary to the clear weight of authority. Although some reported decisions demand that an MDA's "requirement" be device-specific, *see Larsen*, 837 P.2d at 1282; *Ginochio*, 864 F.Supp. at 953; *Oja v. Howmedica, Inc.*, 848 F.Supp. 905, 906-07 (D.Colo.1994), only the Ninth Circuit appears to accept this position,[16]

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[15] Claiming that the PMA procedures are device-specific requirements because they subject each device to particularized attention proves too much. For example, if the device-specific examination of a PMA application under non-specific regulations allows us to characterize the PMA procedures as device-specific, then the individualized examination of a 510(k) application, *see* 21 U.S.C.A. § 360(k); 21 C.F.R. §§ 807.87-807.100, allows us to characterize the 510(k) procedure as device-specific.

[16] While *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846 (2nd Cir.1994) upholds a district court decision requiring device-

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Anguiano, 44 F.3d at 809. Significantly, the First, Third, Fifth, and Eighth Circuits' MDA preemption decisions reject reading any device-specific requirement into § 360k(a) and its regulatory clarification. *See Michael*, 46 F.3d at 1324 (3rd Cir.); *Reeves*, 44 F.3d at 304-05 (5th Cir.); *Martello*, 42 F.3d at 1169 (8th Cir.); *Mendes*, 18 F.3d at 17-19 (1st Cir.).

Nevertheless, our rejection of Appellants' interpretation of the FDA regulations does not remove all significance from the FDA's choice of the word "specific." While a precise definition of what the FDA means by "specific requirements" is neither possible nor desirable, the term must at least narrow the potentially unlimited scope of preemption under § 360k(a). Starting with the plain meaning of the term "specific," defined inter alia as "having a real and fixed relationship to [and] restricted by nature to a particular individual, situation, relation, or effect," Webster's New International Dictionary 2187 (3d ed. 1976), the FDA's call for "specific requirements" under the MDA and the interpretive presumptions against preemption, *see Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2243; *ACF Industries*, — U.S. at ——, 114 S.Ct. at 851; *Silkwood*, 464 U.S. at 251-52, 104 S.Ct. at 623, preclude an overly-broad reading of the Act's preemptive scope.[17] We hold that preemption-trigger-

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specificity, *see Lamontagne v. E.I. Du Pont de Nemours & Co.*, 834 F.Supp. 576, 582-83 (D.Conn.1993), it does so by affirming the district court's dismissal of the complaint on non-preemption grounds and does not address the issue of preemption under the MDA.

[17] For example, equating the FDA's broad power to monitor the medical device market and intervene in the market when necessary, *see, e.g.* 21 U.S.C.A. §§ 331-334, with the type of "specific requirements"

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ing requirements should, in some way, be "restricted by nature" to a particular process, procedure, or device[18] and should not be completely open-ended.

C. Preemption of Appellants' Claims

Having laid out the general rules of preemption under the MDA, we must now conduct a claim-by-claim inquiry to determine whether Appellants' state law claims are preempted.

The MDA preempts a state or local "requirement" which is both "different from, or in addition to" a specific MDA requirement, and "relates to the safety or effectiveness" or "any other matter" included in a specific MDA requirement. 21 U.S.C.A. § 360k(a). *See also* 21 C.F.R. § 808.1(d). We have already determined that state common law claims can impose state requirements within the meaning of the MDA and that these state requirements must be compared with those spe-

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necessitating preemption would stretch the regulation's language, and the preemptive scope of the MDA, beyond the bounds of reason. The possession of jurisdiction is not synonymous with making requirements. A rule equating jurisdiction with preemption-triggering requirements would infer absolute preemption whenever Congress legislates. Such a rule "is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence." *Hillsborough County*, 471 U.S. at 717, 105 S.Ct. at 2377; *Moore*, 867 F.2d at 245.

[18] Device-specific requirements will often be "specific requirements" triggering preemption. *See* 21 C.F.R. § 808.1(d). This does not mean that specific requirements must be device-specific.

cific MDA requirements applicable to the device at the heart of the suit. We must now determine whether Appellants' claims are "different from or in addition to" and "relate to any matter" included in a specific MDA requirement. 21 U.S.C.A. § 360k(a).

The narrow focus of our inquiry should be emphasized. In this section we examine only preemption of state common law claims against the manufacturer of a Class III device which entered the market via the 510(k) process as the substantial equivalent of a grandfathered device. This narrow focus often limits the usefulness of the authorities both parties rely upon. For example, Appellee's heavy reliance on *Stamps*, 984 F.2d 1416, and *King*, 983 F.2d 1130, is misplaced because the device at issue in those cases had undergone the full PMA process before it entered the market.

Our narrow focus also precludes Appellants' reliance on *Smith v. Pingree*, 651 F.2d 1021 (5th Cir., Unit B 1981). First, *Smith* was decided prior to the Supreme Court's *Cipollone* decision and relied on implied preemption principles to reach its decision. *Smith*, 651 F.2d at 1024 (citing *Chemical Specialties Mfrs. Assn., Inc. v. Clark*, 482 F.2d 325, 327 (5th Cir.1973)). *See also id.* at 1025. *Cipollone* made clear that in the absence of some "cause to look beyond" an express preemption provision, implied preemption principles should not be used to decide the preemptive scope of a statute in which Congress provided an express preemption provision.[19] *Cipollone*, — U.S. at ——, 112 S.Ct. at

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[19] We also note that the Fifth Circuit has ignored *Smith* in its post-*Cipollone* MDA preemption cases. *See Reeves*, 44 F.3d 300; *Stamps*, 984 F.2d 1416.

2618. *See also Freightliner*, — U.S. at ——, 115 S.Ct. at 1488. Second, *Smith* is factually distinguishable from the instant case because it considered the preemptive scope of the MDA's Class II regulations on a state regulatory statute. *Smith*, 651 F.2d at 1022 (citing Fla.Stat. §§ 468.135(7); 468.136(1)-(2)). Third and most importantly, the result in *Smith* relies on the fact "that the Florida statute does not relate 'to a matter included in a federal requirement applicable to a device.' " *Smith*, 651 F.2d at 1025 (quoting 21 U.S.C.A. § 360k(a)(2)). *See also id.* at 1024 (holding that § 468.135(7) is not preempted because it addresses a different concern than does the MDA). In other words, *Smith* found that the state statute at issue did not relate to the safety and effectiveness or to "any other matter" within the MDA. *See* 21 U.S.C.A. § 360k(a)(2). In contrast, Appellants cannot seriously dispute that their tort action relates to the safety of the Activitrax. Thus, *Smith* provides no guidance in deciding the case before us.

1. Negligent Design.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently designing and testing the Activitrax pacemaker. Appellants contend that the district court erred by dismissing this claim because the Activitrax and its Model 4011 lead were never subject to any specific requirements under the MDA within the meaning of the Act's preemption provision. Appellee responds that the district court correctly found Appellants' claim preempted because the Activitrax is subject to numerous requirements under the MDA. We conclude that none of the regulations applicable to the Activitrax constitute specific requirements under the MDA and therefore reverse the district court's preemption of Appellants' negligent design claim.

Appellants' Florida law negligent design claim could certainly impose a "State . . . requirement" upon the Activitrax. 21 U.S.C.A. § 360k(a). As explained above, congressional use of the term "requirement" sweeps broadly to encompass common law, as well as statutory and regulatory requirements. *Cipollone*, — U.S. at ——, 112 S.Ct. at 2620, *Duncan*, 12 F.3d at 195. Appellants' negligent design action would ask the jury to decide if Appellee did "something that a reasonably careful person would not do under like circumstances or . . . fail[ed] to do something that a reasonably careful person would do under like circumstances." Florida Standard Jury Instructions in Civil Cases § 4.1. If the MDA establishes specific requirements that apply to the design of the Activitrax, Appellants' action would ask the jury to declare what constitutes a reasonable design after the MDA already set the standard. By doing so, Appellants' claim would be "different from or in addition to" the MDA standard, would "relate . . . to [a] matter included" in the MDA, and would, therefore, be preempted. *See* 21 U.S.C.A. § 360k(a). *See, e.g.*, *National Bank*, 38 F.3d at 991; *Gile*, 22 F.3d at 544; *Slater*, 961 F.2d at 1333. In sum, if the FDA, pursuant to its authority under the MDA, has imposed specific requirements on the Activitrax, a jury cannot add any requirements. *See, e.g.*, *Papas*, 985 F.2d at 518. Appellee identifies four ways in which the MDA allegedly imposes specific requirements on the Activitrax and its Model 4011 lead. We consider each in turn.

First, Appellee insists that the FDA's approval of the Model 4011's 510(k) submission constitutes a finding that the device is safe and effective under the Act—a finding Appellee equates to a specific requirement. Even assuming that a safety and effectiveness finding would constitute a specific design requirement under the MDA, we are not

convinced that 510(k) approval constitutes a finding of safety and effectiveness.

A finding of "substantial equivalence" by the FDA means that the new device has the same intended use as the original device and that the new device either has the same technological characteristics as the original or is demonstrated to be as safe and effective as the original device. 21 U.S.C.A. § 360c(i)(1)(A).[20] Thus, while a substantial equivalence finding can be a finding of safety and effectiveness, there is no way to tell whether a given substantial equivalence finding is a finding of safety and effectiveness. Moreover, the FDA's regulations explain that approval of a device under 510(k) procedures as the substantial equivalent to a grandfathered device "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. This regulation makes obvious sense because the FDA could hardly find a device "as safe and effective" as a grandfathered device whose safety and effectiveness were never established by MDA procedures. *See* 21 U.S.C.A. § 360c(i)(1)(A)(ii)(I). The lack of any official approval under the 510(k) procedure was made clear to Appellee when the Model 4011 was approved in 1982. The FDA's clearance letter, tracking the language of the regulations, cautioned Appellee that "[t]his letter does not in any way denote official FDA approval of your device."

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[20] This section did not exist when the Model 4011 was approved, but we accept for these purposes that the new section only codified the prior practice of the FDA. *See* S.Rep. No. 513, 101st Cong., 2d Sess. 28 (1990).

The regulations governing the form and content of a 510(k) submission state that the "summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence." 21 C.F.R. § 807.92(a). Thus, the MDA's 510(k) submission regulations clarify what should be obvious from the statute: The 510(k) process is focused on equivalence, not safety, and the question of whether a device has been deemed safe and effective cannot be resolved by looking at the 510(k) process, but must be determined by looking at the process through which the original device entered the market. We therefore reject Appellee's argument that 510(k) approval constitutes a finding of safety and effectiveness within the Act.[21] *Cf. National Bank*, 38 F.3d at 998 (Loken, J., concurring) (noting that "an FDA order permitting the new device to be marketed as substantially equivalent to existing devices would not normally reflect agency approval"). We hold that 510(k) approval under the MDA, standing alone, is not a finding of safety and effectiveness and does not impose specific requirements on a device for preemption purposes.

Second, Appellee suggests that by grandfathering pre-MDA devices into the market, the Act recognized their safety and effectiveness as historically established. We disagree. "[T]he absence of a federal standard cannot implicitly extinguish state common law." *Freightliner*, — U.S. at ——, 115 S.Ct. at 1485. Moreover, Appellee identifies nothing in

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[21] Surprisingly, Appellee does not cite to 21 C.F.R. § 807.94, which requires Class III 510(k) submissions to be identified as such. While that regulation provides a scintilla of support to Appellee's argument that a 510(k) submission is a safety and effectiveness finding, it is not enough to overcome our conclusion.

the statute's text, or even in its legislative history, to suggest that grandfathering constitutes a safety and effectiveness finding. Given the strong presumptions against the preemption of state common law claims, we find this argument without merit.

Recognition of the MDA's competing purposes supports our conclusion that grandfathering, without more, cannot justify preemption under the Act. The MDA represents congressional balancing of at least two competing purposes: the desire to protect the public from unsafe devices and the desire to encourage innovation and development in the biomedical technology field. *See, e.g.* H.R.Rep. No. 853, 94th Cong., 2d Sess. 10-11 (1976); S.Rep. No. 33, 94th Cong. 1st Sess. 10 (1975). In light of this balancing, we can view the MDA as a compromise between device manufacturers and Congress. In exchange for the financial and time burdens placed upon manufacturers by the MDA, the manufacturers were assured a nationally uniform and predictable regulatory and liability climate. A rule preempting liability based on grandfathering would give the benefits of a uniform, predictable liability climate to devices that never paid the MDA's regulatory "price" for market entry. Additionally, allowing state tort suits based upon the failure of pre-MDA devices would not disturb a manufacturer's developmental calculus because presumably, when such devices were first introduced, the devices were considered a wise business investment despite state-imposed tort liability. In short, preempting claims against grandfathered pre-MDA devices would give their manufacturers a regulatory windfall.

Third, Appellee points to continued FDA surveillance of devices like the Activitrax as constituting specific requirements under the Act. *See, e.g.*, 21 C.F.R. §§ 807.81(a)(3)(i) (requiring FDA approval for any design changes); 895.25 (granting FDA authority to order labeling changes). As already explained above, these provisions cannot constitute specific requirements within the meaning of the MDA's preemption regulation. At best, they are general requirements because they have no "fixed relationship" and are not "restricted by nature to" a particular process, procedure, or device. *See* Webster's New International Dictionary 2187 (3d ed. 1976). In light of the presumption against preemption, the FDA's jurisdiction to monitor the market is too slender a regulatory strand to support preemption.

Finally, Appellee suggests that MDA procedures for classifying devices impose specific requirements. *See* 21 U.S.C.A. § 360c(a); 21 C.F.R. § 860.7. As we have previously noted, a "requirement" is best understood as "something called for or demanded." Webster's New International Dictionary 1929 (3d ed. 1976). Putting a device into Class III, without more, places no demands on the device's manufacturer. *Accord National Bank*, 38 F.3d at 997. The classification of devices under the Act is similar to a regulatory census; while the classification may have significant regulatory consequences, it creates no requirements by itself.

Accordingly, we hold that Appellants' negligent design claim is not preempted by the MDA because the Act does not establish any specific design requirements, through a finding of safety and effectiveness or otherwise, which conflict with the state law claim.

2. Negligent Manufacture.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently manufacturing and assembling the Activitrax and Model 4011. The district court found that the MDA preempted this negligent manufacturing claim. After reviewing the requirements the MDA places on

the manufacturing processes of suppliers like Appellee, we affirm the district court.

Like their negligent design claim, Appellants' negligent manufacturing claim could create state requirements because it would ask a jury to determine how a reasonable manufacturer should build the Activitrax. Therefore, the negligent manufacturing claim is preempted if the jury could create a standard of conduct "different from, or in addition to" a specific MDA requirement. *See* 21 U.S.C.A. § 360k(a).

As we have already concluded, nothing in the MDA's 510(k) approval procedures, grandfathering provision, oversight and enforcement powers, or classification requirements constitutes a "specific requirement" justifying preemption under the Act. *See* 21 C.F.R. § 808.1(d). In the case of manufacturing, however, Appellee also points to the MDA's good manufacturing practice (GMP) regulations as specific requirements justifying preemption. *See* 21 U.S.C.A. § 360j(f); 21 C.F.R. §§ 820.1-820.198.

The GMP regulations monitor the "methods used in, and facilities and controls used for, the manufacture, pre-production design validation (. . . but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device . . . to assure that the device will be safe and effective. . . ." 21 U.S.C.A. § 360j(f)(1)(A). As the statute's text makes clear, although GMP requirements do not evaluate the safety and effectiveness of the device, the GMP requirements do ensure that the manufacturing, packing, and other processes associated with a manufacturing enterprise are conducted safely and effectively. *Id.* The GMP regulations include requirements affecting a manufacturer's organization, personnel, building, equipment, component controls, production and process controls, packaging, labeling controls, holding, distribution, installation, device evaluation, and record keeping. *See* 21 C.F.R. §§ 820.20-820.198.

We believe the GMP requirements are specific requirements which preempt Appellants' negligent manufacturing claim. *Accord Michael*, 46 F.3d at 1324; *Mendes*, 18 F.3d at 19. While the requirements are not device- specific, they are certainly specific to manufacturing. Moreover, while the GMP regulations are written in necessarily broad language[22] to accommodate the myriad of different producers covered by the MDA, the GMP regulations create standards for almost every aspect of the manufacturing process. *See* 21 C.F.R. §§ 820.20-820.198. The FDA's forfeiture actions against non-complying manufacturers foreclose any suggestion that the GMP regulations are hortatory and without substantive effect. *See, e.g., United States v. Laerdal Manufacturing Corp.*, 853 F.Supp. 1219, 1222-23, 1227-35 (D.Or.1994); *United States v. Undetermined Quantities of Var. Articles*, 800 F.Supp. 499, 502-503 (S.D.Tex.1992); *United States v. 789 Cases*, 799 F.Supp. 1275, 1287-1293 (D.Puerto Rico 1992).

Appellants' negligent manufacturing claim constitutes a state requirement "different from, or in addition to" the GMP regulations' specific manufacturing requirements. We therefore hold that the district court properly granted summary judgment on this claim because it is preempted by the MDA.

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[22] For example, the regulation on personal sanitation within buildings states: Washing and toilet facilities shall be clean and adequate. Where special clothing requirements are necessary to assure that a device is fit for its intended use, clean dressing rooms shall be provided for personnel. 21 C.F.R. § 820.56(a).

3. Negligent Failure to Warn.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently failing to warn and instruct Ms. Lohr or her physicians about the dangers of the Activitrax pacemaker. The district court found that the MDA preempted this claim. A review of the MDA's warning and labeling requirements convinces us that the district court was correct.

Like their other negligence claims, Appellants' failure to warn claim could constitute a "State . . . requirement" and is preempted if the jury could conclude that a reasonable manufacturer's warnings and labels would be "different from, or in addition to" a specific MDA requirement. *See* 21 U.S.C.A. § 360k(a). Nothing in the MDA's 510(k) approval procedure, grandfathering provision, oversight and enforcement powers, or classification requirements constitute "specific requirements" justifying preemption under the Act. *See* 21 C.F.R. § 808.1(d). Like the manufacturing claim, however, Appellee points to additional MDA regulations governing labeling as specific requirements justifying preemption. *See* 21 C.F.R. §§ 801.109, 807.87(e).

Every prescription device like the Activitrax must comply with an MDA imposed labeling requirement. 21 C.F.R. § 801.109. The label on the device itself must inform the reader about the prescription-only nature of the device and the method of its application or use. 21 C.F.R. § 801.109(b). More importantly, labeling "on or within" the device's packaging must contain (1) usage information, "including indications, effects, routes, methods, and frequency and duration of administration," and (2) warning information, including any "relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c). The FDA screens the premarket submissions of all devices for compliance with la-

beling requirements, including 510(k) submissions. 21 C.F.R. § 807.87(e).

We believe these labeling requirements constitute specific requirements for preemption purposes. *Accord Michael*, 46 F.3d at 1324; *Reeves*, 44 F.3d at 305; *Mendes*, 18 F.3d at 18. As we have made clear, the labeling regulations' lack of device specificity does not dictate that they cannot be specific requirements for preemption purposes. Instead, the regulations are quite specific about what standards a manufacturer must follow when designing the packaging and labeling for its product. *See* 21 C.F.R. § 801.109(b), (c). As with the GMP regulations discussed above, the fact that the regulations are broadly phrased does not obviate their effectiveness, but rather reflects the need to encompass many thousands of devices within their requirements. Further, the FDA's record of taking action against mislabeled devices forecloses the argument that the Act's labeling requirements lack substantive "bite." *See, e.g.*, *United States v. Various Articles of Device*, 814 F.Supp. 32, 33 (E.D.Tenn.1992); *United States v. Articles of Device [Acuflex; Pro-Med]*, 426 F.Supp. 366, 370-71 (W.D.Penn. 1977).

Appellants' failure to warn claim constitutes a state requirement "different from, or in addition to" the MDA's specific labeling requirements. We therefore hold that the district court properly granted summary judgment on this claim because it is preempted by the MDA.

4. Strict Liability in Tort.

Appellants' complaint alleged that Appellee is strictly liable for Lora Lohr's injuries because it introduced an unreasonably dangerous product—the Activitrax—into the market. As with Appellants' other claims, the district court concluded that the MDA preempted this claim. A comparison of

Florida's strict liability law and the regulatory scheme applicable to the Activitrax convinces us that the district court was incorrect and that Appellants' strict liability claim, insofar as it alleges that the Activitrax and Model 4011 are unreasonably dangerous as designed, should be allowed to proceed.

Like Appellants' other claims, a Florida strict liability action could impose a "State ... requirement" on the Activitrax. 21 U.S.C.A. § 360k(a). A strict products liability action under Florida law would ask the jury "whether the [Activitrax] supplied by [Appellee] was defective when it left the possession of [Appellee]." Florida Standard Jury Instructions, § PL. The jury can find a product defective "if it is in a condition unreasonably dangerous to the user [and reaches] the user without substantial change" or "if by reason of its design the product is in a condition unreasonably dangerous to the user [and reaches] the user without substantial change." Florida Standard Jury Instructions, §§ PL 4, PL 5. A product may be unreasonably dangerous due to defects in its design, manufacture, or labeling. *See, e.g., Radiation Technology, Inc. v. Ware Const. Co.*, 445 So.2d 329, 331 (Fla.1983); *Brown v. Glade and Grove Supply, Inc.*, 647 So.2d 1033, 1035 (Fla.App.1994).

Under Florida's strict liability doctrine, the burden of rendering a product safe is placed in the hands of the entities "in a better position to ensure the safety of the products." *Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, 1068 (Fla.1993). A finding that defects in a product render it unreasonably dangerous is necessarily a finding that the product is unsafe. The word "dangerous" itself is defined in terms of safety: "exposing to danger, involving risk, demanding caution or care as extremely unsafe." Webster's New International Dictionary 573 (3d ed. 1976). Thus, if the MDA establishes specific requirements designed to avoid

having unsafe products reach users, then Appellants' strict liability action would be "different from, or in addition to" the MDA standard and is therefore preempted. *See* 21 U.S.C.A. § 360k(a).

Our analysis of Appellants' three negligence claims guides our strict liability inquiry. Because the 510(k) process, grandfathering provision, oversight and enforcement powers, and classification requirements do not impose specific safety requirements on the Activitrax's design, it follows that they do not prevent that design from creating an unreasonably dangerous product. In contrast, because the GMP and labeling requirements create standards of care for manufacturing and labeling drafted to ensure that devices are manufactured and labeled in a safe manner, it follows that these requirements should prevent the manufacturing or labeling of the Activitrax from creating an unreasonably dangerous product.[23]

Accordingly, we hold that Appellants' strict liability claim arising from an allegedly unreasonably dangerous design is not preempted, but any contentions that the manufacture or labeling of the Activitrax created an unreasonably dangerous product are preempted by the MDA. On remand, the district court should ensure that Appellants' strict liability claim is limited to proving that the Activitrax and Model 4011 lead are unreasonably dangerous as designed.

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[23] Preempting strict liability claims arising from some processes, but not others, is consistent with Florida caselaw. *See ISK Biotech Corp. v. Douberly*, 640 So.2d 85, 88-89 (Fla.App.1994) (preempting, under FIFRA, failure to warn claim but allowing strict liability claim "based solely on the product's defective condition" to proceed); *Brennan v. Dow Chemical Co.*, 613 So.2d 131, 132 (Fla.App.1993) (same).

Appellants should not be allowed to revive their preempted negligent manufacturing and failure to warn claims in the form of a strict liability claim.

III. CONCLUSION

The Court's decision to preempt some, but not all of Appellants' claims is sure to please neither party. Nevertheless, as the Supreme Court noted in a recent preemption decision, "[t]he middle course we adopt seems to us best calculated to carry out the congressional design." *Wolens*, — U.S. at ——, 115 S.Ct. at 827. Any displeasure with that design should be directed toward Congress. The lines and distinctions we draw in today's decision are not always neat or easy, but "in our system of adjudication, principles seldom can be settled 'on the basis of one or two cases, but require a closer working out.' " *Id.* (quoting Pound, Survey of the Conference Problems, 14 U.Cin.L.Rev. 324, 339 (1940)).

In conclusion, we hold that the district court properly held that Appellants' negligent manufacture and negligent failure to warn claims are preempted by the MDA. But the district court erred when it held Appellants' negligent design claim and strict liability claim arising from an unreasonably dangerous design were preempted by the Act.

AFFIRMED in part, REVERSED in part, and REMANDED.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
March 16, 1994

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Reconsideration or Certification (Doc. No. 48, filed January 25, 1994). Plaintiffs responded in opposition on February 1, 1994 (Doc. No. 49).

On February 15, 1994, the Court directed the parties to submit supplemental memoranda addressing the applicability of the recently issued per curiam opinion in the consolidated cases *Duncan v. Iolab Corp.* and *Rogers v. Optical Radiation Corp.*, 12 F.3d 194 (llth Cir. 1994). In this opinion, dated January 24, 1994, the court of appeals followed the Seventh Circuit in holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act of 1938 preempted the plaintiffs' state law claims for negligence, strict liability in tort, and breach of implied warranty.

Plaintiff contends that *Duncan* decision is distinguishable for the following reasons: (1) *Duncan* involved an intraocular lens, as opposed to the cardiac pacemaker lead at issue in the instant matter; (2) Plaintiff Lora Lohr never signed a consent form, unlike the plaintiff in *Duncan*; and (3) Congress never expected the FDA to grant an investigation-device exemption to the instant pacemaker leads, as the FDA had done with the lens in *Duncan*. Defendant contends that *Duncan* is analogous to the instant case and is controlling precedent.

The Court agrees with Defendant's assertion. The distinctions offered by Plaintiff, all purely factual, do not rebut the clear language of *Duncan*, in which the court of appeals made no attempt to distinguish between different products. The court simply held that section 360(k) of the Medical Device Amendments of 1976 ("the MDA") to the Food, Drug and Cosmetic Act of 1938 preempts state law claims for negligence, strict liability in tort, and breach of implied warranty. The pacemaker lead in the instant matter was specifically regulated under the MDA.

On December 17, 1993, when the Court issued its Order denying Defendant's Motion for Summary Judgment (Doc. No. 45), it was not clearly established within this circuit that claims such as those pled by Plaintiffs were preempted by the MDA. As *Duncan* explicitly sets forth that such claims *are* preempted, this Court must give effect to that decision, which is binding precedent.

Accordingly, the Motion to Reconsider (Doc. No. 48) is **GRANTED.** The Court's prior Order denying Defendant's Motion for Summary Judgment (Doc. No. 45) is VACATED, and Defendant's Motion for Summary Judgment hereby is **GRANTED.** Defendant's alternative Motion for Certification (Doc. No. 48) is **MOOTED.**

The Clerk is directed to: (1) enter Judgment on behalf of Defendant; (2) tax costs accordingly; and (3) close the file.

DONE AND ORDERED at Jacksonville, Florida, this 16th day of March, 1994.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Copies to:

Robert F. Spohrer, Esq.
Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

Garry Randolph

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
Feb. 16, 1994

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Reconsideration or Certification (Doc. No. 48, filed January 25, 1994). Plaintiffs responded in opposition on February 1, 1994 (Doc. No. 49).

It appears to the Court that neither party may be aware of the issuance of a per curiam opinion by the Eleventh Circuit in *Duncan v. Iolab Corp.*, No. 92-2620 (consolidated with *Rogers v. Optical Radiation Corp.*, No. 92-2801). In this opinion, dated January 24, 1994, the court of appeals followed the Seventh Circuit in holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act of 1938 preempted the plaintiffs' state law claims for negligence, strict liability in tort, and breach of implied warranty. The opinion was scheduled to issue as mandate on February 15, 1994.

The Court will defer ruling on Defendant's Motion until the parties have had an opportunity to comment on the applicability of this recent decision to the case at bar. Accordingly, on or before March 1, 1994, each party shall simultaneously file *brief* memoranda addressing the applicability of *Duncan* to the instant case.

DONE AND ORDERED at Jacksonville, Florida, this 15th day of February, 1994.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Attachment
Copies to:

Robert F. Spohrer, Esq.
Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

Law Clerk

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
Dec. 17, 1993

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Summary Judgment (Doc. No. 36, filed November 1, 1993). Plaintiffs filed a response in opposition on November 12, 1993 (Doc. No. 43).

Defendant is the manufacturer of an allegedly defective cardiac pacemaker lead which allegedly caused or contributed to injuries to Plaintiff Lora Lohr. Plaintiffs filed this action in state court, setting forth claims of negligence, strict liability and breach of warranty by Defendant, alleging, inter alia, that the pacemaker and the attached leads were made of defective materials and contained metallurgical defects. After the matter was removed to this Court, the claim for breach of warranty (Count III) was dismissed.

In the instant Motion, Defendant argues that its pacemaker device, the Medtronic Model 4011, has been approved

for sale and use by the Food and Drug Administration ("FDA"), and that such approval preempts any state cause of action such as is brought in the instant lawsuit. Plaintiffs contend in opposition that there is no federal preemption and, therefore, that their suit under state law should be allowed to proceed.

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories and admission on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of showing the Court, by reference to materials on file that there are no genuine issues of material fact that should be decided at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Clark v. Coats & Clark, Inc.*, 929 F.2d 604 (11th Cir. 1991). A moving party discharges its burden on a motion for summary judgment by "showing" or "pointing out" to the Court that there is an absence of evidence to support the nonmoving party's case. *Celotex*, 477 U.S. at 325. Rule 56 permits the moving party to discharge its burden with or without supporting affidavits and to move for summary judgment on the case as a whole or on any claim. *Id.* When a moving party has discharged its burden, the nonmoving party must then "go beyond the pleadings," and by its own affidavits, or by "depositions, answers to interrogatories, and admissions on file," designate specific facts showing that there is a genuine issue for trial. *Id.* at 324.

In determining whether the moving party has met its burden of establishing that there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law, the Court must draw inferences from the evidence in the light most favorable to the nonmovant, *Key West Harbor v. City of Key West*, 987 F.2d 723, 726 (11th Cir. 1993), and re-

solve all reasonable doubts in that party's favor. *Spence v. Zimmerman*, 873 F.2d 256, 257 (11th Cir. 1989). The nonmovant need not be given the benefit of every inference, but only of every "reasonable" inference. *Brown v. City of Clewiston*, 848 F.2d 1534, 1540 n.12 (11th Cir. 1988). The Eleventh Circuit has explained the reasonableness standard:

> In deciding whether an inference is reasonable, the Court must "cull the universe of possible inferences from the facts established by weighing each against the abstract standard of reasonableness." [citation omitted]. The opposing party's inferences need not be more probable than those inferences in favor of the movant to create a factual dispute, so long as they reasonably may be drawn from the facts. When more than one inference reasonably can be drawn, it is for the trier of fact to determine the proper one.

WSB-TV v. Lee, 842 F.2d 1266, 1270 (11th Cir. 1988).

Thus, if a reasonable fact finder evaluating the evidence could draw more than one inference from the facts, and if that inference introduces a genuine issue of material fact, then the court should not grant the summary judgment motion. *Augusta Iron and Steel Works v. Employers Insurance of Wausau*, 835 F.2d 855, 856 (11th Cir. 1988). It must be emphasized that the mere existence of *some* alleged factual dispute will not defeat an otherwise properly supported summary judgment motion. Rather, "the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A dispute about a material fact is "genuine" if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. The inquiry is "whether the evidence presents a sufficient disagreement to require submission to a

jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52.

The Court is not presently confronted with the existence of any "factual" disputes which might otherwise preclude entry of summary judgment. Rather, the Court must simply resolve the legal issue of whether the Plaintiffs' claims are preempted under the federal regulatory scheme. In any pre-emption analysis, the intent of Congress "is the ultimate touchstone." *Cipollone v. Liggett Group., Inc.*, 112 S. Ct. 2608, 2617 (1992) (citations omitted). Or, as stated in the same term *Cipollone* was decided:

> Pre-emption may be either expressed or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. Absent explicit pre-emptive language, we have recognized at least two types of implied pre-emption: field pre-emption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict pre-emption, where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the full purposes and objectives of Congress.

Gade v. National Solid Wastes Management Ass'n, 112 S. Ct. 2374, 2383 (1992) (citations and quotations omitted) (cited in *Public Health Trust v. Lake Aircraft*, 992 F.2d 291, 294 (llth Cir. 1993)). Thus, unless it is the "clear and manifest purpose of Congress" that state law be superseded, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), there is a strong presumption against federal preemption, *Cipollone*, 112 S. Ct. at 2617; *P.R. Consumer Affairs Dep't v. Isla Petroleum*, 485 U.S. 495, 500 (1988).

Upon review of the Motion, the Memorandum of Law submitted therewith, and the opposition filed thereto, the Court concludes that the instant matter is not federally pre-empted. The Court strongly concurs with Plaintiff that "regulation" does not equal "preemption." This is particularly true where, as here, the federal regulatory provision provides no cause of action or remedies for an allegedly defective product. Defendant's Model 4011 was approved by the FDA, and is subject to regulation by the Medical Device Amendment Act of 1976 ("MDA"). Florida law, which might provide relief to Plaintiffs should they ultimately prevail—the likelihood of which remains unknown—simply does not "stand[ ] as an obstacle to the full purposes and objectives of Congress." *Gade*, 112 S. Ct. at 2383.[1] Moreover, the Court notes that the basis of Plaintiffs' action is not the fact that this pacemaker was prescribed for use by the treating physician(s), but rather that the *manufacturer* did not conform to the federal regulations which Defendant believes preempt the action. While the federal government has approved the *use* of this and similar devices, the Court is not convinced that the government intended to take from Plaintiffs the opportunity to show that the product was defectively *manufactured*.

Accordingly, the Motion (Doc. No. 36) hereby is **DENIED.**

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[1] It would indeed be paradoxically unjust if the effect of federal *approval* and *regulation*—a scheme existing presumably to *prevent* or lessen the chance of product defects—would be to consistently bar mere access to the courts for (potential, if provable) relief from those defects.

DONE AND ORDERED at Jacksonville, Florida, this 17th day of December, 1993.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Copies to:

Robert F. Spohrer, Esq.
Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

IN THE UNITED STATES COURT OF APPEAL
FOR THE ELEVENTH CIRCUIT

No. 94-2516

Filed
Aug. 15, 1995

LORA LOHR, MICHAEL LOHR, her husband,

Plaintiffs-Appellants,

versus

MEDTRONIC, INC., a foreign corporation,

Defendant-Appellee.

On Appeal from the United States District Court for the Middle District of Florida

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ON PETITION(S) FOR REHEARING AND SUGGESTION(S) OF REHEARING EN BANC (Opinion _____, 11th Cir., 19 _, _____ F.2d _____).

Before: BLACK and BARKETT, Circuit Judges, and RONEY, Senior Circuit Judge.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no member of this panel nor other Judge in regular active service on the

Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 35-5), the Suggestion(s) of Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/S/
UNITED STATES CIRCUIT JUDGE

21 U.S.C. § 360(k) (1994)

§ 360. Registration of producers of drugs or devices

. . . .

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

21 U.S.C. § 360k (1994)

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 807.81(a)(3) (1995)

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

. . . .

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

. . . .

21 C.F.R. § 807.87 (1995)

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all informa-

tion known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

21 C.F.R. § 808.1(d) (1995) (excerpt)

. . . .

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

. . . .

21 C.F.R. § 870.3680(b), (c) (1995)

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

. . . .

(b) Permanent pacemaker electrode—

(1) Identification. A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical

stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.